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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,983	11/28/2000	Scott A. Waldman	100051.10161	8378
35148	7590	05/11/2009		
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER YAO, LEI	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 05/11/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/724,983

**Applicant(s)**

WALDMAN, SCOTT A.

**Examiner**

LEI YAO

**Art Unit**

1642

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23, 28-30, 36 and 50-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 28-30, 36 and 50-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-884)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 2/20/2009, 4/21/2009, and 5/1/2009



**Request for Continued Examination**

The request filed on 2/9/2009 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No.09724983 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 23, 28-30, 36 and 50-89 are pending and are examined on the merits for a method of treating metastatic colorectal cancer comprising administering ST receptor antibody.

***Information Disclosure Statement***

The information disclosure statement (s) (IDS) submitted on 4/20/2009, 4/21/2009, and 5/1/2009 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**New Matter Rejection:**

Claims 23, 28-30, 36 and 50-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that base claim 23-a), is amended to recite “....ST receptor ligand (antibody) in an amount to cause a cytotoxic or cytostatic effect on metastasized colorectal cancer cells..... ”, which is not supported by the instant specification. The instant specification as filed, teaches the claimed method comprising administering a conjugated composition of ST receptor binding moiety (antibody) and an active moiety comprising a chemotherapeutic agent or a toxin to cause cytotoxic or cytostatic effect on metastasized colorectal cancer (page 36-37). Thus, causing cytotoxic or cytostatic effect on cancer cell is due to the chemotherapeutic agent or the toxin in the conjugate, not a ST receptor ligand, an antibody. The specification does not teach that a ST antibody or receptor ligand has cytotoxic or cytostatic effect on any cell including a colorectal cell, therefore, does not provide sufficient support for the instant claims as amended.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 23, 28-30, 36, and 50-89 remain and are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 9, 10, 28-34, 38-42, 46-49 and 55-58 of U.S. Patent No. 5,879,656. Although the conflicting claims are not identical, they are not patentably distinct from each other as stated below:

The instant claims 23, 28-30, 36, and 50-80 are drawn to a method of treating metastasized colorectal cancer comprising administering said individual a therapeutically effective amount of pharmaceutical composition comprising a) a ST receptor antibody or Fab or F(AB)<sub>2</sub> and b) an active agent comprising a chemotherapeutic agent or a toxin (claims 23, 28-30, 36, and 50-80). The instant claims 81-89 are drawn to the same preamble method above comprising administering a conjugated compound comprising the reagents a) and b) above.

The claims of US Patent 5879656 ('656) are drawn to a method of treating an individual having metastasized colorectal cancer comprising administering said individual a conjugated compound comprising ST receptor binding moiety and an active moiety, wherein the ST receptor binding moiety is ST antibody or Fab or F(ab)<sub>2</sub> and the active moiety is a chemotherapeutic agent, a toxin or a radioactive agent.

The claims of '656 Patent teach the same method steps for treating the same patients with the same materials (conjugate) as the instant claims 81-89 and would

anticipate the instant claimed invention. Regarding the instant claims 23, 28-30, 36, and 50-80, the claims of '656 Patent disclose the method of treating the same patients with the same materials. The only difference is claims of '656 Patent using conjugate of a ST receptor binding moiety comprising ST receptor antibody and an active agent, while the instant claims do not. It would have been obvious to modify the method of '656 Patent to treat the same patient with the same materials without conjugating them together if each ST antibody and active agent self could cause a cytotoxic or cytostatic effect on metastasized colorectal cancer cells as stated in the instant claims. One skilled in the art would have been motivated with expectation of success to administer the two compounds in a pharmaceutical composition in order to save the step of conjugating and to arrive instant claimed invention with expected result.

2. Claims 23, 28-29, 36, 50-60, 63-65, 67-78, 81-85, and 89 remain and are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6060037 ('037). Although the conflicting claims are not identical, they are not patentably distinct from each other as stated in the previous office action and again below:

The instant claims are drawn to a method of treating metastasized colorectal cancer comprising administering said individual a therapeutically effective amount of pharmaceutical composition comprising **a)** a ST receptor antibody and **b)** an active agent comprising an active agent or a toxin (claims 23, 28-30, 36, and 50-80) or a conjugate of the reagents of a and b.

The claims of US Patent '037 teaches a method of treating a individual having metastasized colorectal cancer comprising administering said individual a therapeutically effective amount of pharmaceutical composition comprising a conjugated compound comprising ST receptor binding moiety and an active moiety that cause cell death, wherein said active moiety is a radiostable active agent.

The claims of US Patent '037 although do not teach the species of that ST receptor binding moiety, one skilled in the art would understand that "a receptor binding moiety" is a small genus including its ligand and antibody to the receptor, which is also evidenced by the specification of US Patent '037 teaching the ST receptor binding moiety including antibody, Fabs, or F(ab)<sub>2</sub>, that specifically binds to ST receptor (col 11, line 5+).

Thus, the claims of 'US Patent '037 teach the method of treating the same patients with the same materials. The only difference is the claims of '037 Patent using a conjugate of a ST receptor moiety and an active agent, whereas the instant claims do not. It would have been obvious to modify the method of '037 Patent to treat the same patient with the same materials without conjugating them together if each ST antibody and active agent self could cause a cytotoxic or cytostatic effect on metastasized colorectal cancer cells. One skilled in the art would have been motivated with expectation of success to administer the two compounds in a pharmaceutical composition in order to save the step of conjugating and to arrive instant claimed invention with expected result.



Applicant states that a Terminal Disclaimer will be provided as appropriate.

Thus, the rejections are maintained and made again stated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/  
Examiner, Art Unit 1642

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643